

**REMARKS**

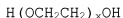
No claims have been amended herein. Accordingly, claims 1-8, 10, 12-17, 20-33, 35-40, 42, 44-47, 50-64, and 66-74 are pending. Applicants respectfully request reconsideration and allowance of all pending claims.

**1. Rejections under 35 U.S.C. §103(a) over Krzysik, et al., in view of Gatto, et al., further in view of Bartels**

Reconsideration is requested of the rejection of claims 1-8, 10, 12-17, 20-22, 25-30, 32, 33, 35-40, 42, 44-47, 50-55, 58-60, 62-64, 66, 68, and 70-74 under 35 U.S.C. §103(a) as being unpatentable over Krzysik, et al. (WO 00/64409, hereinafter referred to as "Krzysik, et al.") in view of Gatto, et al (US 6570054, hereinafter referred to as "Gatto et al."), further in view of Bartels (US 20030157195, hereinafter referred to as "Bartels").

Claim 1 is directed to an absorbent product comprising an absorbent substrate and a moisturizing and lubricating composition. The moisturizing and lubricating composition comprises: from about 1% (by weight) to about 40% (by weight) of an emollient, from about 1% (by weight) to about 20% (by weight) of a humectant, from about 30% (by weight) to about 90% (by weight) an immobilizing agent, from about 0.05% (by weight) to about 5% (by weight) of an antioxidant, and from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent, wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least

about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C. The immobilizing agent is a high molecular weight polyethylene glycol having the formula:



wherein x is the degree of ethoxylation and is an average value of at least about 20 moles. The moisturizing and lubricating composition is at least about 40% soluble/dispersible in deionized water at a temperature of about 80°C. The antioxidant is selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, gamma oryzanol, sodium sulfite, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, proanthocyanidins, and mixtures thereof.

Krzysik, et al. disclose **skin barrier enhancing** absorbent tissues comprising a lipid-enriched melted hydrophilic composition. The composition comprises a hydrophilic solvent, a high molecular weight polyethylene glycol, a fatty alcohol ( $\text{C}_{14}$ - $\text{C}_{30}$  or greater), a humectant, an oil-in-water emulsifying surfactant having an HLB range greater than 7, a sterol, and a natural fat or oil. Specifically, in one exemplary embodiment, the composition comprises from about 10 to about 95 weight percent hydrophilic solvent, from about 5 to about 95 weight percent high molecular weight polyethylene glycol (preferably having a molecular weight of 720 or greater), from about 1 to about 30 weight percent of humectant, from about 1 to about 20

weight percent emulsifying surfactant having an HLB range greater than 7, from about 0.1 to about 10 weight percent of sterol or sterol derivative, and from about 0.1 to about 30 weight percent of natural fats or oils. Additional ingredients, such as antioxidants, may be added to the composition. After the composition is applied to a tissue, the composition is resolidified to form a distribution, preferably a uniform distribution, of solid deposits on the surface of the tissue.

Significantly, Krzysik, et al. fail to teach or suggest from about 0.05% (by weight) to about 5% (by weight) of an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), carotenoids, gamma oryzanol, sodium sulfite, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, proanthocyanidins, and mixtures thereof, as required by Applicants' claims. More particularly, Krzysik, et al. fail to teach any amount of any specific antioxidant in their composition.

Recognizing the above deficiencies, the Office combines Gatto, et al. and Bartels with Krzysik, et al. to arrive at each and every limitation of Applicants' claimed invention. Gatto, et al., disclose an absorbent article having a stable skin care composition. The skin care composition contains at least one skin care ingredient and one rheological agent for stabilizing the composition. Gatto, et al., disclose that BHT is one of several ingredients that may be incorporated as a preservative<sup>1</sup>.

Bartels discloses a topical composition and method for treatment of the symptoms of diaper rashes and skin irritations

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<sup>1</sup> See, Gatto, et al., column 24, line 65 - column 25, line 4.

caused by acidic secretions.<sup>2</sup> The topical composition comprises: a pH-raising ingredient; an anhydrous base ointment; polysorbate 80; a pharmaceutically acceptable diluent; and butylated hydroxytoluene (BHT).<sup>3</sup> Embodiments of Bartels include a cream, dusting powder, spray, bath soak and effervescent tablet, and a bodyside diaper liner.<sup>4</sup>

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. § 2142 requires a clear articulation of the reasons why the claimed invention would have been obvious. Specifically, the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385, 1396 (2007) noted that the burden lies initially with the Office to provide an explicit analysis supporting a rejection under 35 U.S.C. 103. "[R]ejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."<sup>5</sup> The Court in *KSR International* further identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham v. John Deere Co.* (383 U.S. 1, 148 USPQ 459 (1966)). Specifically, as previously required by the TSM (teaching, suggestion, motivation) approach to obviousness, one exemplary rationale indicated requires some teaching, suggestion, or motivation in the prior art reference that would

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<sup>2</sup> Bartels, at abstract.

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

have led one of ordinary skill to modify the prior art reference to arrive at the claimed invention.

Specifically, to reject a claim based on this rationale, the Office must articulate the following: (1) a finding that there was some teaching, suggestion, or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at each and every limitation of the claimed invention; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. The Office has failed to meet its burden under number (1) above, as there is no apparent reason for one skilled in the art to combine and/or modify the cited references to arrive at each and every limitation. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Specifically, the common sense of one ordinarily skilled in the art would not have provided a reason to combine the Krzysik, et al. reference, the Gatto, et al. reference, and the Bartels reference to arrive at Applicants' composition of claim 1. Initially, Krzysik, et al. only generally disclose the inclusion of an antioxidant in a list of twenty-four optional ingredients, and nowhere disclose a suitable amount. As such, why would one skilled in the art be motivated to include the **optional**

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<sup>5</sup> In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

antioxidant of Krzysik, et al. in Applicants' claimed amounts, and further, why would one be motivated to specifically choose an antioxidant as required by Applicants' amended claim 1 when Krzysik, et al. nowhere mention any specific antioxidants? One skilled in the art simply would not and could not be so motivated.

Moreover, as noted in M.P.E.P. § 2142, in establishing obviousness, the Office must show references that teach all of the claimed limitations along with some reason, either in the references themselves or in knowledge generally available to one skilled in the art, to modify and/or combine the references and arrive at the claimed subject matter. The mere fact that the references can be modified and combined to arrive at the claimed subject matter does not render the resultant combination obvious, unless the prior art also suggests a reason for the combination. *In re Mill*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). While this test is not a rigid formula, it does provide helpful insight as it can be important to identify a reason that would have prompted a person of ordinary skill in the art to modify the elements as the new invention does.

Applicants respectfully submit that a close reading of the cited references clearly indicates that one skilled in the art would not have been so motivated and, without Applicants' disclosure as a blueprint (which the Office had the benefit of utilizing), such a combination of the formulations of the Krzysik, et al., Gatto, et al., and Bartels references would not

have been made.<sup>6</sup> Specifically, a close reading of Gatto, et al. and Bartels would direct one skilled in the art away from a combination with Krzysik, et al. More particularly, the Krzysik, et al. reference focuses on a product that transfers a formulation to the user's skin to provide, maintain, and aid recovery of the skin barrier function<sup>7</sup>; that is, the formulation of Krzysik, et al. is specifically a skin barrier enhancing formulation. Gatto, et al. and Bartels, conversely, teach away from barrier-type creams and formulations. Specifically, Gatto, et al. discloses that creams and lotions for providing physical barrier protection are occlusive and not very effective once a full blown case of inflammation or dermatitis has developed<sup>8</sup>, and as such, its invention uses a skin care composition having skin care ingredients for providing visible skin benefits to diapered skin (i.e., providing smooth, silky, non-grainy skin feel to minimize abrasion of sensitive or compromised skin having chronic conditions such as chaffing, dryness, or rashes)<sup>9</sup> and at least one rheological agent for stabilizing the composition such that agglomeration, stratification, and/or settling of the

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<sup>6</sup> M.P.E.P. § 2142 further provides that in order to reach a proper determination under 35 U.S.C. §103(a), the Examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. Knowledge of Applicants' disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences." The tendency to resort to "hindsight" based upon Applicants' disclosure is often difficult to avoid due to the very nature of the examination process. However, as stated by the Federal Circuit, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. Grain Processing Corp. v. American-Maize-Products, Co., 840 F.2d 902, 904 (Fed. Cir. 1988).

<sup>7</sup> Krzysik, page 2, lines 65-68 and page 3, lines 70-91.

<sup>8</sup> See, Gatto, col. 1, lines 52-58.

<sup>9</sup> Id., col. 7, lines 21-24.

composition are minimized. Further, Bartels mentions that its invention "does not purport or attempt to be a barrier cream (emphasis added),"<sup>10</sup> and the invention is looking for a "method besides barrier creams"<sup>11</sup> (emphasis added) to treat diaper rashes. Thus, why would one having ordinary skill in the art interested in improving barrier function, as Krzysik, et al. is attempting to do, look to references that specifically mention the undesirability of simply enhancing barrier function? Put another way, if Gatto, et al. and Bartels are specifically looking for different methods as an alternative to barrier creams, why would one skilled in the art looking to improve barrier function, be motivated to use the compositions of Gatto, et al. and Bartels? Applicants' respectfully assert that it would simply not have been obvious to one having ordinary skill in the art to combine Krzysik, et al., Gatto, et al., and Bartels.

With all due respect, it appears that the Office has used impermissible hindsight analysis and reconstruction when combining the Krzysik, et al., Gatto, et al., and Bartels references. What is important is that there is no guidance provided by the cited references to arrive at such a specific combination.

Based on the foregoing, claim 1 is patentable over the cited references. Claims 2-8, 10, 12-17, 20-22, 25-30, and 72 depend from claim 1 and are therefore patentable over the cited

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<sup>10</sup> Bartels, para. [0033].

<sup>11</sup> *Id.* at para. [0011].



references for the same reasons as set forth above for claim 1, as well as for the additional elements they require.

Independent claim 32 is similar to claim 1 and further requires the moisturizing and lubricating composition to comprise a dispersing agent. As such, claim 32 is patentable over the cited reference for the same reasons as set forth above for claim 1, as well as for the additional limitations it requires.

Claims 33, 35-40, 42, 44-47, 50-55, 58-60, and 73 depend directly or indirectly from claim 32 and are therefore patentable over the cited reference for the same reasons as set forth above for claim 32, as well as for the additional elements they require.

Claim 62 is similar to claim 1 and further requires the immobilizing agent to be a high molecular weight polyethylene glycol selected from the group consisting of PEG 3350, PEG 6000, PEG 8000, and PEG 10,000. As such, claim 62 is patentable over the cited reference for the same reasons as claim 1, as well as for the additional limitations it requires.

Claims 63, 64, 66, 68, and 74, which depend from claim 62, are patentable over the cited reference for the same reasons as claim 62, as well as for the additional limitations they require.

Claim 70 is similar to claim 1 and further requires the humectant to be selected from the group consisting of N-Acetyl ethanolamine, urocanic acid, aloe vera gel, arginine PCA, chitosan PCA, copper PCA, corn glycerides, dimethyl imidazolidinone, fructose, glucamine, glucose, glucose

glutamate, glucuronic acid, glutamic acid, glycereth-7, glycereth-12, glycereth-20, glycereth-26, honey, hydrogenated honey, hydrogenated starch hydrolysates, hydrolyzed corn starch, lactamide MEA, lactic acid, lactose lysine PCA, mannitol, methyl gluceth-10, methyl gluceth-20, PCA, PEG-2 lactamide, PEG-10 propylene glycol, polyamino sugar condensate, potassium PCA, propylene glycol citrate, polyamino acid, polysaccharide, saccharide hydrolysate, saccharide isomerate, sodium aspartate, sodium lactate, sodium PCA, sorbitol, TEA-lactate, TEA-PCA, Urea, Xylitol, and mixtures thereof. Claim 70 is thus patentable over the cited reference for the same reasons as set forth above for claim 1, as well as for the additional limitations it requires.

Claim 71, which depends from claim 70, is patentable over the cited reference for the same reasons as claim 70, as well as for the additional limitations it requires.

**2. Rejections under 35 U.S.C. §103(a) over Krzysik, et al. in view of Gatto, et al., further in view of Bartels, in view of Bowser, et al.**

Reconsideration is requested of the rejection of claims 1, 23, 24, 32, 56, 57, 62, and 67 under 35 U.S.C. §103(a) as being unpatentable over Krzysik, et al. in view of Gatto, et al. further in view of Bartels and in view of Bowser, et al. (US 5,342,976, hereinafter referred to as "Bowser, et al.").

Claim 1 is discussed above.

Krzysik, et al., Gatto, et al. and Bartels are discussed above. Significantly, Krzysik, et al., Gatto, et al. and

Bartels, alone or in combination, fail to disclose or suggest a composition including from about 0.05% (by weight) to about 5% (by weight) of an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, gamma oryzanol, sodium sulfite, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, proanthocyanidins, and mixtures thereof. Bowser, et al. fail to overcome this shortcoming.

Specifically, Bowser, et al. is directed to a composition suitable for topical application to human skin. The composition comprises an active ingredient that can control skin barrier functions; particularly, the active ingredient can moisturize and treat skin surfaces that have become excessively dry, fissured, eroded, or otherwise damaged. One such active ingredient disclosed by Bowser, et al. is a ceramide. In one embodiment, the compositions can be used in a liquid-impregnated fabric, such as a tissue wipe.

While Applicants acknowledge that Bowser, et al. disclose a ceramide that may treat skin surfaces, Bowser, et al. does not overcome the shortcomings of the other cited prior art. Significantly, Bowser, et al. fail to teach or suggest a composition comprising from about 0.05% (by weight) to about 5% (by weight) of an antioxidant, particularly an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, gamma oryzanol, sodium sulfite, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, proanthocyanidins,

and mixtures thereof. As such, claim 1 is submitted to be patentable over the cited references.

Claims 23 and 24 depend from claim 1 and are therefore patentable over the cited references for the same reasons as set forth above for claim 1, as well as for the additional elements they require.

Independent claim 32 is similar to claim 1 and further requires the moisturizing and lubricating composition to comprise a dispersing agent. As such, claim 32 is patentable over the cited references for the same reasons as set forth above for claim 1, as well as for the additional limitations it requires.

Claims 56 and 57 depend directly or indirectly from claim 32 and are therefore patentable over the cited references for the same reasons as set forth above for claim 32 as well as for the additional elements they require.

Claim 62 is similar to claim 1 and further requires the immobilizing agent to be a high molecular weight polyethylene glycol selected from the group consisting of PEG 3350, PEG 6000, PEG 8000, and PEG 10,000. As such, claim 62 is patentable over the cited references for the same reasons as claim 1, as well as for the additional limitations it requires.

Claim 67 which depends from claim 62, is patentable over the cited references for the same reasons as claim 62, as well as for the additional limitations it requires.

**3. Rejections under 35 U.S.C. § 103(a) over Krzysik, et al. in view of Gatto, et al., in view of Bartels, in view of Vega, et al.**

Reconsideration is requested of the rejection of claims 1, 31, 61, and 69 under 35 U.S.C. § 103(a) as being unpatentable over Krzysik, et al. in view of Gatto, et al., in view of Bartels, in view of Vega, et al. (U.S. Patent No. 6,153,209, hereinafter referred to as "Vega").

Claim 1, as currently amended, is discussed above.

The Krzysik, et al., Gatto, et al. and Bartels references are discussed above. Significantly, Krzysik, et al., Gatto, et al., and Bartels, alone or in combination, fail to disclose or suggest a composition including from about 0.05% (by weight) to about 5% (by weight) of an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxyltoluene (BHT), carotenoids, gamma oryzanol, sodium sulfite, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, proanthrocyanidins, and mixtures thereof. Vega, et al. fail to overcome this shortcoming.

The Office cites Vega, et al. because it discloses the particular absorbent products in Applicants' claims 31, 61 and 69. Specifically, Vega, et al. is directed to absorbent articles having a skin care composition deposited on at least a portion of the article. The skin care composition is a breathable, barrier protectant which can be immobilized on the article and is transferable to the wearer's skin via contact, normal wearer motion, and/or body heat. The skin care composition may comprise an emollient an immobilizing agent, and

optionally a humectant. The absorbent product disclosed by Vega, et al. is a diaper (col. 1, line 7).

As with the Krzysik, et al. reference, Gatto, et al., Bartels, and Vega, et al. fail to disclose a composition comprising from about 0.05% (by weight) to about 5% (by weight) of an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, gamma oryzanol, sodium sulfite, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, proanthocyanidins, and mixtures thereof. As such, claim 1 is submitted to be patentable over the cited references.

Claim 31 depends from claim 1 and is therefore patentable over the cited references for the same reasons as set forth above for claim 1, as well as for the additional elements it requires.

Independent claim 32 is similar to claim 1 and further requires the moisturizing and lubricating composition to comprise a dispersing agent. As such, claim 32 is patentable over the cited references for the same reasons as set forth above for claim 1, as well as for the additional limitations it requires. Claim 61 depends from claim 32 and is therefore patentable over the cited references for the same reasons as set forth above for claim 32 as well as for the additional elements it requires.

Claim 62 is similar to claim 1 and further requires the immobilizing agent to be a high molecular weight polyethylene glycol selected from the group consisting of PEG 3350, PEG 6000, PEG 8000, and PEG 10,000. As such, claim 62 is patentable over

the cited references for the same reasons as claim 1, as well as for the additional limitations it requires. Claim 69 which depends from claim 62, is patentable over the cited references for the same reasons as claim 62, as well as for the additional limitations it requires.

**4. Double Patenting Rejections**

Claims 1-8, 10, 12-17, 35-40, 42, and 44-74 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-59 of copending Application No. 10/659,862.

Applicants note this rejection is in fact a provisional obviousness-type double patenting rejection since U.S. Patent Application No. 10/659,862 has not yet issued as a patent. Applicants will address the merits of these rejections, as appropriate, if the listed application issues as a patent before the application at hand.

**CONCLUSION**

In light of the foregoing, Applicants request withdrawal of the rejections of claims 1-8, 10, 12-17, 20-33, 35-40, 42, and 44-47, 50-64, 66-74 and allowance of all pending claims. The Commissioner is hereby authorized to charge any government fees which may be required during the entire pendency of this application to Deposit Account No. 01-2384.

Respectfully Submitted,

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